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Abstract

Objectives

To study barriers and facilitators to implementation of Mindfulness-Based Stress Reduction (MBSR) for people with MS.

Methods

Qualitative interviews were used to explore barriers and facilitators to implementation of MBSR, including 33 people with MS, 6 MS clinicians and 2 course instructors. Normalisation Process Theory (NPT) provided the underpinning conceptual framework. Data was analysed deductively using NPT constructs (coherence, cognitive participation, collective action, and reflexive monitoring).

Results

Key barriers included: mismatched stakeholder expectations; lack of knowledge about MBSR; high levels of comorbidity and disability; and skepticism about embedding MBSR in routine MS care. Facilitators to implementation included: introducing a pre-course orientation session; adaptations to MBSR to accommodate comorbidity and disability; and participants suggested smaller, shorter classes, shortened practices, exclusion of mindful-walking, and more time with peers. Post-MBSR booster sessions may be required, and objective and subjective reports of benefit would increase clinician confidence in MBSR.

Discussion

MS patients and clinicians know little about MBSR. Mismatched expectations are

a barrier to participation, as is rigid application of MBSR in the context of disability. Course adaptations in response to patient needs would facilitate uptake and utilisation. Rendering access to MBSR rapid and flexible could facilitate implementation. Embedded outcome assessment is desirable.

Background

Multiple sclerosis (MS) is a complex, poorly understood, chronic neurodegenerative condition ¹. Prognostic uncertainty, event unpredictability, complex drug treatment regimens, varied physical and cognitive impairments, and associated social and role limitations in MS can lead to stress ². In turn, stress in MS may diminish quality of life (QOL) ³, impact adversely on mood ⁴, and potentially increase likelihood of disease relapse ⁵. Prevalence of mental health comorbidity in MS is very high ⁶, and national clinical practice guidelines emphasise an integrative approach to management in general ⁷. Effective stress management interventions for people with MS are few and far between, and novel treatments that are acceptable to patients, clinically and cost-effective, and implementable in contemporary health services are clearly required ⁸.

Mindfulness-based interventions (MBIs) are increasingly used in healthcare settings ⁹. Mindfulness as a healthcare intervention has been defined as '*paying attention in a particular way: on purpose, in the present moment, and non-judgmentally*' ¹⁰. MBIs derive largely from Mindfulness-Based Stress Reduction (MBSR), introduced in the ~~nineteen-eighties~~ 1980s by Jon-Kabat-Zinn. The most commonly used and widely studied MBIs are MBSR and Mindfulness-Based Cognitive Therapy (MBCT). Both MBSR and MBCT teach mindfulness through core meditation exercises and group psychoeducation ^{11, 12}. MBIs are by definition complex interventions, with multiple potential active components (numerous and diverse meditation exercises, psychoeducation, group format) ¹³. How they work is largely unknown, but recent models provide insights from a combined psychological and neural perspective ¹⁴. MBIs have good quality

evidence for treating stress and mental health comorbidities in other long-term conditions (LTCs) ¹⁵, and there is some preliminary evidence to suggest acceptability, clinical and cost-effectiveness in people with MS ¹⁶⁻¹⁸. Given elevated levels of mental health comorbidity among people with MS and existing high quality evidence for MBI effectiveness in addressing symptoms of anxiety and depression in non-MS populations, introducing a MBI suited to the complex needs of MS patients makes sense. However, how best to deliver and implement MBIs to diverse MS populations remains uncertain with no published studies in this area ¹⁹.

Implementation is a complex phenomenon ^{20, 21}, constituting a continuum of ‘diffusion-dissemination-implementation’; diffusion is a passive process,, dissemination is active, and implementation focuses on the integration of new practices in new contexts/settings ²². Existing studies suggest that the implementation of MBIs in the UK NHS is a challenging and complex process ²³. On the ‘macro-’ level, implementation can mean socio-politico-cultural change; on a ‘meso-’ level, teams may need to work together in a novel way; and on a ‘micro-’ level, the agents of change are individuals ²².

The UK Medical Research Council (MRC) guidance ¹³ for developing and evaluating complex interventions suggests that implementation should be theory-based. If a theoretical basis is lacking, working out how/why implementation processes are successful or otherwise is difficult. It has been suggested by theorists that decision makers in healthcare should assess a novel

intervention's '*workability, clinical- and cost- effectiveness*', and whether it can '*integrate*' into existing organisational paradigms and practices ²⁴.

In this study, the theoretical 'lens' of Normalisation Process Theory (NPT) ²⁵ was used to assess implementation of a bespoke (tailored) MBSR course for people with MS in the UK NHS. NPT is a research method designed for studying the implementation of complex interventions in healthcare ²⁶. It is a sociologically derived action theory that can be used to assess how new interventions are undertaken by those people implementing them. It is a flexible tool, usable in feasibility studies for delineating potential individual, collective, and resource issues faced when introducing novel complex interventions.

NPT was developed as an implementation science theory to provide insight and understanding of factors influencing implementation ²¹. This type of theory is in contrast to process models and determinant frameworks that seek to describe/guide the translation of research into practice and predict outcomes ²¹.

NPT has been widely used ²⁷ and can be used to highlight implementation facilitators and barriers in early stage feasibility and development work. It does not set out to evaluate implementation success/failure per se in the same way that evaluation frameworks do ²¹, but can help to estimate the likelihood of incorporation into routine practice. NPT suggests four main areas of behavior that should be considered (Figure 1):

Figure 1 – NPT core constructs

Aim

The aim of this study was to examine barriers and facilitators to the implementation of a MBSR course for people with MS.

Methods

The methods used were based on the MRC guidelines¹³ for developing and evaluating complex interventions. This study utilised data derived from nested semi-structured qualitative interviews (n=43) associated with a feasibility wait-list randomised controlled trial (RCT) testing MBSR against usual care¹⁶. This entailed two successive groups of 25 people with MS receiving MBSR (total n=50); the first group received standard MBSR (Additional file 5); the second a version of MBSR with optimisation changes based on feedback from group 1. Full details of optimisation changes and of quantitative findings from the RCT have been described elsewhere^{16,28}.

All interviews were conducted on a one-to-one basis. Participants and MBSR instructors were interviewed after the MBSR courses using NPT-informed interview questions (Additional files 1-3) that sought to determine optimisation steps to improve acceptability and accessibility of the intervention for people with MS²⁸ and to explore issues that might impact on implementation. Of those 33 participants interviewed, seven had not completed their MBSR course. In the present study, data was further scrutinised under the deductive theoretical 'lens' of a NPT coding matrix (Table 1) in order to address the implementation issues in relation to using MBSR in those affected by MS. It is important to note that no

attempt was made to make the data fit the theory; any which did not would be coded outside the framework as appropriate.

In addition, six other key stakeholders (Consultant Neurologist, MS Specialist Nurse, Neuropsychologist, Rehabilitation Medicine Consultant, Specialist in Integrative Medicine, Complementary Therapist) were interviewed to ascertain their views on potential implementation issues. Questions were based on the four main areas of NPT, assessing understanding of MBSR, support for the intervention, what role MBSR might play in routine MS care, barriers and facilitators to operationalising the course and how it should be assessed (Additional file 4). Data arising from these stakeholders were coded deductively, directly under NPT headings (Table 1).

Table 1 – NPT coding matrix

Results

Mean (SD) participant age was 44.3 (11.0), most (29/33; 88%) were female, all were of 'White Scottish' ethnicity, with a median (range) postcode derived socioeconomic status (SES) of 4 (1-10) (1 delineating the most deprived, 10 the least). The majority (20/33; 61%) had university level education. Disability, as measured by the Expanded Disability Status Scale (EDSS), had a mean (SD) value of 4.4 (1.8). The majority (22/33; 67%) had relapsing-remitting MS (RRMS), but all disease phenotypes were represented in the sample. Participants had a mean (SD) comorbidity count of 3.6 (2.7). MBSR session attendance rates (out of a possible eight) ranged from one to eight. There were a total of six interviewees who had not completed the course.

Key implementation issues related to stakeholder perspectives of the MBSR course (coherence); their ability or willingness to engage with the intervention (cognitive participation); the practical steps that were required to undertake MBSR (collective action); and how they judged the intervention (reflexive monitoring)

Coherence – making sense of MBSR

Prior to engaging in the course, most participants did not have a clear understanding of what MBSR was and how it might help them. Many took part in the hope of reducing stress, chronic pain or helping with sleep. However, a minority identified the quite unique focus of the course as a barrier to participation. Feedback suggested that the mindfulness approach placed too

much emphasis on disabling aspects of MS, which was uncomfortable. On the other hand, one participant felt too little had been done to accommodate wheelchair users in the group setting. Following organisational problems with the first group (use of an upstairs room with limited disabled access and one of two disabled toilets being out of commission) and an apparent lack of knowledge among participants about what to expect from the eight-week course, the instructors introduced an orientation session to the second group, which was well received. A greater emphasis was placed on conveying to participants what the course would involve, the amount and type of home practice that they would be asked to complete, and how participation would be each individual's own responsibility.

Striking a balance was difficult for the instructors. They acknowledged MS as a defining characteristic for participants, but were keen to avoid supporting what they saw as a strong illness identity, feeling that MBSR was a well-honed generic approach, suitable for most people, and that learning to be 'mindful' and more self-compassionate would benefit participants in this study. Participants' valued acknowledgement of the difficulties associated with MS, especially disability (physical and mental). One participant expected a much clearer focus on MS in course content and materials (Additional file 6, Quote 1)

Most clinical stakeholders supported the view that managing stress effectively was important for quality care in MS. However, some were unsure what taking part in a MBI would entail for their patients, the underlying theory and empirical evidence to support its use. One clinician, the specialist Neuropsychologist,

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2
3 already used tailored mindfulness concepts in her treatment formulations. She
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5 felt that MBIs could help with general symptom management and with
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7 acceptance towards the condition, but cautioned the importance of setting
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9 realistic expectations (Additional file 6, Quote 2).
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11 12 13 14 ***Cognitive participation – engaging with the MBSR intervention*** 15

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18 The initial recruitment target of 50 people in this study was met within the 12-
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20 week recruitment window, suggesting participants were willing to accept the
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22 idea of MBSR. However, relatively high levels of attrition (40%) from the courses
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24 were most evident early on, raising questions about what prevented sustained
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26 involvement. Factors such as disability and comorbid LTCs (chronic pain,
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28 fatigue) hampered engagement in some cases, where movement was challenging,
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30 or sitting for long periods difficult. However, some participants clearly did not
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32 find the mindfulness approach intuitive or acceptable, preferring not to focus
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34 additional attention on their condition (Additional file 6, Quote 3).
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40 Taking part in the MBSR programme was a big commitment of time and effort,
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42 including managing logistics like arranging child care, or transportation.
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44 Experiencing benefit from the practices, getting encouragement from the course
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46 instructors, MS clinicians, or important others (parents, partners) all helped
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48 promote uptake and participation in the sessions. Many appear to have accepted
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50 the view that MBSR could help them become more accepting of their condition,
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52 altering how they related to their experiences, particularly unpleasant
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54 embodiment sensations. Several participants reported being more ‘mindful’ and
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compassionate, a finding in keeping with quantitative findings from the associated feasibility RCT in which they had taken part.

All clinicians interviewed were willing to support the idea of mindfulness, recognising a need for stress management resources for their patients. Several identified a lack of clear-cut pathways for accessing MBIs as a potential implementation barrier. All clinicians expressed the view that MBI instructors should be appropriately qualified, ideally having prior experience of working with people with MS (Additional file 6, Quote 4).

All clinician stakeholders interviewed for the study cited busy clinical schedules and lack of funding resources as limitations to implementation of MBSR for people with MS (Additional file 6, Quote 5).

Collective action - practical steps to undertaking MBSR

In addition to commonly reported issues of finding time and space to keep up MBSR practice, participants in this study also reported that disability and comorbid LTCs hampered engagement. Furthermore, due to difficulties with balance and co-ordination, many participants found mindful-walking challenging, citing a fear of falling. For some of the wheelchair users who could not walk, the name 'mindful walking' was unacceptable and identified as a barrier to taking part.

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3 One participant with fatigue could not tolerate in-depth questioning ('enquiry')
4 about her experience of the practices. Others described that chronic pain
5 prevented sitting or lying for prolonged periods in meditation. A participant with
6 ataxia described how a perceived scrutiny on impairment heightened his self-
7 consciousness, preventing participation (Additional file 6, Quote 6).
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16 The instructors' were keen to avoid participants dwelling on what they saw as an
17 unhelpful MS illness identity. They wanted everyone taking part to feel included
18 and accommodated for, recognising a need to cautiously tailor the practices
19 accordingly, and mindfully bring attention to what each individual could do, as
20 opposed to couldn't (Additional file 6, Quote 7).
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29 The instructors talked about shortening practices for participants who were
30 struggling, increasing duration as confidence and tolerance grew. After mindful-
31 walking was poorly received in the first group it was subsequently re-branded as
32 'mindful-locomotion' for the second, which the instructors felt was a more
33 inclusive term for wheelchair users. Similarly, mindful movement postures were
34 simplified and adapted for standing, seated, or lying positions.
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45 Both MBSR instructors had to make time to lead the courses, over and above
46 their usual clinical activities in integrative care. They had to negotiate with
47 service managers to facilitate the courses, worked through their lunchtime to fit
48 in the extra activity, and sought to recruit nursing staff to help with more
49 disabled patients in the groups.
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All clinicians interviewed reported a desire to help improve their patients' mental health and thought that MBSR could potentially help. Like some participants, clinicians wanted such resources on hand at times of increased stress and vulnerability (Additional file 6, Quotes 8, 9).

One clinician lamented a perceived mind-body dichotomy in the NHS as hampering access to such interventions and contributing to a lack of service provision, in his view an oversight in strategic planning (Additional file 6, Quote 10). This clinician felt that addressing the service gap via the creation of a MBI would make his job in MS rehabilitation much easier, but hesitated that inflexibility in application (i.e. a limited treatment duration with no follow-up) would decrease the likelihood of his referral.

Reflexive monitoring - judging the MBSR course

In this study, participants suggested various modifications to MBSR, such as using a more accessible room, providing an orientation session, making the class sizes smaller, shortening the sessions and the meditation practices, and providing more time for social bonding with peers, exclusion of mindful walking, and making the course manual more MS-specific and disability-friendly. Several expressed a desire to have ongoing access to MBSR post-completion (Additional file 6, Quote 11).

In this study there were no formal arrangements for 'follow-up' at course completion, raising an important question about continuity of care after finishing

up the MBSR course. In their normal clinical role of teaching MBSR, the course instructors routinely telephoned non-attenders as a means of managing clinical risk. They described how such checks allowed insight into problematic issues with course organisation, structure, perceived focus, and content. They also sought 'informal' written participant feedback during courses, which helped with intervention fidelity, and allowed them to address issues with the course as they emerged. This proved useful in the MBSR courses for people with MS, where mindful walking was not well received, and the mindful movement practices required modification (Additional file 6, Quote 12).

All clinicians felt that validated outcome measurement was necessary, with most suggesting assessment of QOL and mental health as paramount. Other suggestions included formal feedback from those running the course, in terms of how the participant had managed in the MBSR sessions and whether goals of treatment had been attained (Additional file 6, Quote 13).

In terms of reconfiguring the course, two clinicians highlighted that group settings were not appropriate for all patients and that in such circumstances a one-to-one alternative should be made available. This was reflected by some participant accounts of initial anxiety about being in a group, but finding the format increasingly acceptable as familiarity grew. One clinician, echoing participant views, suggested implementation had to be flexible and, like the course participants and MBSR instructors, several clinicians felt ongoing access to the MBI through 'booster' sessions would be helpful.

Discussion

Summary of key findings

Using NPT as a conceptual framework, this study identified key facilitators and barriers to the implementation of a bespoke MBSR course for people with MS.

Participants and MBSR instructors initially had mismatched expectations of MBSR in this study. Participants expected a greater emphasis on MS, while the course instructors saw MBSR as a well-honed generic approach to managing stress, suitable in its standard format for people with MS. Participants did not know what to expect from MBSR, with some expecting a greater focus on MS, others a greater acknowledgement of disability. The MBSR instructors had to adapt to address participant expectations. Some participants found this disappointing and perhaps this hindered their engagement. MS clinicians recognised stress as a problem for their patients, identified the importance of setting treatment goals, but knew little about MBSR.

People with MS and their clinicians both acknowledge the need for stress management resources. For participants, a clear understanding, in advance, of likely benefits from MBSR, level of commitment of time and effort required, and how to do the practices correctly in the context of disability seems critical. Those delivering MBSR in this context should consider that adaptations to the course setting, materials and delivery might be required to improve engagement. Clinicians stress the importance of a familiarity with MS for those delivering such courses. This may require additional training.

Generic MBSR courses/materials do not appear to be optimal for people with disability and certain comorbid LTCs. Practicing MBSR when individuals have chronic pain, fatigue, or impaired mobility may not be practicable or safe if implemented in a rigid manner. In such a context, MBSR instructors should plan ahead when dealing with disabled and/or multimorbid groups, and must be sensitive and flexible in branding and application of the mindfulness practices. MS clinicians and patients alike desire effective mental health interventions at times of emotional crises, but some clinicians question organisational support for such a service.

MBSR courses for people with MS ought to have routine safety and governance measures in place. As suggested by both instructors and clinicians in this study, these should include standard follow-up procedures and embedded continuity of care. Routine outcome measurement allied with feedback from those taking part can usefully inform adaptive modifications to courses designed for people with complex disabilities. Several participants, instructors and clinicians suggested follow-up booster sessions as important.

Comparison with existing literature

No previous research has systematically addressed barriers and facilitators to implementing MBIs for people with MS. Byron et al.²⁹ have recently evaluated implementation of staff training in MBSR in adolescent mental health units, while Amaro³⁰ has described implementation challenges in developing a MBSR course for people with substance use disorders (SUD). Elsewhere, implementation

challenges facing MBCT for people with recurrent depression has been rigorously researched ²³.

Rycroft-Malone et al. ²³ studied MBCT implementation in the UK NHS, firstly using qualitative interviews with course participants across 40 distinct areas in the UK, and secondly by conducting 10 case studies in each of the four home nations, with further qualitative interviews with key stakeholders (NHS commissioners, managers, MBCT instructors, and course participants). Data were analysed using the Promoting Action on Research in Health Services (PARIHS) framework. Findings included that provision of MBCT was patchy across the UK, that stakeholders regularly adapted the course to suit local needs, that management 'buy-in' was helpful, but inconsistent, and that individual champions often emerged to drive forward implementation, sometimes over several years. Indeed, successful implementation seemed to rely on implementation champions (often 'bottom-up' individuals) who could facilitate 'top-down' organisational support. Byron et al. ²⁹, studying the implementation of MBI training for mental health staff, also identified the importance of such a champion. No clear champion was identified in this current study, with MS clinician stakeholders citing busy clinical schedules and a lack of funding and resources.

As per findings from this current study, Rycroft-Malone et al. ²³ found that dissemination of evidence supporting the intervention was a crucial and longitudinal task, whilst Byron et al. ²⁹ found this occurred on multiple levels, 'vertically' in leadership structures, and 'horizontally' via staff networks, both

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2
3 working to spread innovative practices through the organisational hierarchy and
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5 culture. Like Rycroft-Malone et al. ²³, who looked at MBCT for recurrent
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7 depression, Kopke et al. ³¹ found that implementation of patient education
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9 programmes for MS relapse management could fail where clinician stakeholders
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11 did not understand the rationale of a novel complex intervention, even where
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13 evidence of effectiveness is apparent.
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18 Rycroft Malone et al. ²³ also described how MBCT instructor training and
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20 supervision was identified as a further challenge, whereby working with distinct
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22 clinical groups other than those with recurrent depression could necessitate
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24 additional knowledge and skills. Amaro ³⁰ also cited this as an important
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26 consideration when implementing an adapted MBSR course for people with SUD,
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28 where ‘cultural fit’ and ‘ecological validity’ required attention. In this context
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30 participants received MBSR very poorly initially, with engagement only
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32 improving once specific needs of participants were taken into account. The
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34 course manual required simplification, initial practices had to be shortened to
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36 help facilitate an experience of ‘success’, and time spent in group discussion had
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38 to be increased to cover how the practices could relate to triggers and cravings.
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40
41 Kopke et al. ³¹ found that lack of identification with a novel complex intervention
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43 (a MS relapse management patient education programme) was an important
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45 implementation barrier for course instructors, while Amaro ³⁰ identified that
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47 MBSR facilitators should be experienced in dealing with SUD, as participants
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49 often brought common problems associated with this to the course sessions for
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51 discussion.
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Strengths and weaknesses

A strength is that this study is part of a wider body of work examining the use of MBIs among people with MS, including a nationally representative epidemiological study of comorbidity in MS ⁶, a systematic review of MBI effectiveness in MS ¹⁷, a feasibility RCT ¹⁶, and parallel qualitative process evaluation ²⁸. A wide range of stakeholder opinions was sought. However, not all participants that took part in the MBSR courses were interviewed, nor the full range of clinicians involved in MS care (e.g. Allied Health Professionals, GPs), and their views could potentially add another dimension to barriers and facilitators in this context.

This study used a theory driven approach to assessing barriers and facilitators to implementation of a bespoke MBI for people with MS. NPT was specifically designed for the study of factors affecting implementation of complex interventions in healthcare. Use of such a theoretical framework is in keeping with best recommended practice ¹³. However, guarding against ‘shoehorning’ data into any pre-defined tool is necessary. In this study, prior inductive coding of participant and MBSR instructor data via thematic analysis protects somewhat against this potential pitfall, but did not apply equally in the case of other stakeholder data, which was coded directly under NPT headings, although the research team was mindful of this as an issue.

Very little is known about the implementation of MBIs for people with MS specifically, with no published studies in this area. Thus comparison has necessarily been limited to findings from the implementation of MBCT for

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2
3 recurrent depression, MBSR in adolescent mental health settings, and MBSR for
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5 people with SUD. Important theoretical differences exist when making this
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7 comparison, in that the MS population is likely to be more physically disabled,
8
9 with high levels of physical and mental health comorbidity ⁶.
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11 12 13 14 **Conclusions**

15
16 Setting clear expectations by making the theory, benefits, and practical aspects of
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18 taking part in MBSR clear to MS patients and clinicians alike may facilitate
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20 implementation. Participants and clinicians value acknowledgement of MS and
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22 disability awareness by those delivering MBSR. Based on participant feedback,
23
24 judicious course adaptations to accommodate disability are required and further
25
26 training for instructors may be necessary. Clinicians desire clear-cut referral
27
28 pathways and rendering access to MBSR responsive (rapid and flexible) to
29
30 patient needs (at times of distress) could facilitate implementation. Embedding
31
32 routine outcome measurement is desirable and may usefully contribute to
33
34 implementation of an optimised MBSR course for people with MS.
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45 took part in this study.
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51
52 available online at: <http://theses.gla.ac.uk/7893/>
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Authors' contributions

Stewart Mercer, Frances Mair, and Robert Simpson (RS) conceived this study. RS carried out the literature search. RS, Sharon Byrne and Karen Wood carried out data collection, and analysis, with input from all authors. RS wrote the first draft of the paper, but all authors contributed to the final version. All authors read and approved the final manuscript.

Declaration of conflicting interests

The authors declare that they have no competing interests.

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Consent for publication

Not applicable.

Ethics approval and consent to participate

NHS Lothian Research Ethics Council (REC reference number: 14/SS/0091) and NHS Greater Glasgow and Clyde (study ID number: GN14CH078) granted full

prospective ethical approval for this study prior to any stakeholder interviews taking place. All participants gave written informed consent to take part. The study was registered with [Clinicaltrials.gov](https://clinicaltrials.gov) (<https://clinicaltrials.gov/ct2/show/NCT02136485>).

References

1. Ramagopalan SV, Dobson R, Meier UC and Giovannoni G. Multiple sclerosis: risk factors, prodromes, and potential causal pathways. *The Lancet Neurology*. 2010; 9: 727-39.
2. Dennison L, Moss-Morris R and Chalder T. A review of psychological correlates of adjustment in patients with multiple sclerosis. *Clinical psychology review*. 2009; 29: 141-53.
3. Wollin JA, Spencer N, McDonald E, Fulcher G, Bourne M and Simmons RD. Longitudinal changes in quality of life and related psychosocial variables in Australians with multiple sclerosis. *International journal of MS care*. 2013; 15: 90-7.
4. Feinstein A. Multiple sclerosis and depression. *Multiple Sclerosis Journal*. 2011; 17: 1276-81.
5. Mohr DC, Hart SL, Julian L, Cox D and Pelletier D. Association between stressful life events and exacerbation in multiple sclerosis: a meta-analysis. *Bmj*. 2004; 328: 731.
6. Simpson RJ, McLean G, Guthrie B, Mair F and Mercer SW. Physical and mental health comorbidity is common in people with multiple sclerosis: nationally representative cross-sectional population database analysis. *BMC neurology*. 2014; 14: 128.
7. Excellence NIHaC. Multiple sclerosis in adults: management. *NICE guidelines*. <https://www.nice.org.uk/guidance/cg1862014>.
8. Fiest K, Walker J, Bernstein C, et al. Systematic review and meta-analysis of interventions for depression and anxiety in persons with multiple sclerosis. *Multiple Sclerosis and Related Disorders*. 2016; 5: 12-26.
9. Goyal M, Singh S, Sibinga EM, et al. Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. *JAMA internal medicine*. 2014; 174: 357-68.
10. Kabat-Zinn J. *Wherever you go, there you are: Mindfulness meditation in everyday life*. Hyperion, 1994.
11. Kabat-Zinn J. Full catastrophe living: The program of the stress reduction clinic at the University of Massachusetts Medical Center. *New York: Delta*. 1990.
12. Segal ZV, Williams JMG and Teasdale JD. *Mindfulness-based cognitive therapy for depression*. Guilford Press, 2012.
13. Craig PD, P; MacIntyre, S; et. al. Developing and evaluating complex interventions: new guidance. *Medical Research Council*. Online: Medical Research Council UK, 2008.

14. Tang Y-Y, Hölzel BK and Posner MI. The neuroscience of mindfulness meditation. *Nature Reviews Neuroscience*. 2015; 16: 213-25.
15. Fjorback L, Arendt M, Ørnbøl E, Fink P and Walach H. Mindfulness - Based Stress Reduction and Mindfulness - Based Cognitive Therapy-a systematic review of randomized controlled trials. *Acta Psychiatrica Scandinavica*. 2011; 124: 102-19.
16. Simpson R, Mair FS and Mercer SW. Mindfulness-based stress reduction for people with multiple sclerosis-a feasibility randomised controlled trial. *BMC neurology*. 2017; 17: 94.
17. Simpson R, Booth J, Lawrence M, Byrne S, Mair F and Mercer S. Mindfulness based interventions in multiple sclerosis-a systematic review. *BMC neurology*. 2014; 14: 15.
18. Bogosian A, Chadwick P, Windgassen S, et al. Distress improves after mindfulness training for progressive MS: A pilot randomised trial. *Multiple Sclerosis Journal*. 2015: 1352458515576261.
19. Simpson R, Mair F and Mercer S. Mindfulness-based interventions for people with multiple sclerosis. *Multiple Sclerosis Journal*. 2015: 1352458515579702.
20. May C, Rapley, T., Mair, F.S., Treweek, S. Murray, E., Ballini, L., MacFarlane, A., Girling, and Finch, T.L. Normalization Process Theory On-line Users' Manual, Toolkit and NoMAD instrument. 2015.
21. Nilsen P. Making sense of implementation theories, models and frameworks. *Implementation Science*. 2015; 10: 53.
22. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA and Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009; 4: 50.
23. Rycroft-Malone J, Gradinger F, Griffiths H, et al. Accessibility and implementation in the UK NHS services of an effective depression relapse prevention programme: learning from mindfulness-based cognitive therapy through a mixed-methods study. 2017.
24. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC health services research*. 2006; 6: 1.
25. May C and Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology*. 2009; 43: 535-54.
26. Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC medicine*. 2010; 8: 1.
27. McEvoy R, Ballini L, Maltoni S, O'Donnell CA, Mair FS and MacFarlane A. A qualitative systematic review of studies using the normalization process theory to research implementation processes. *Implementation Science*. 2014; 9: 2.
28. Simpson R, Byrne S, Wood K, Mair FS and Mercer SW. Optimising mindfulness-based stress reduction for people with multiple sclerosis. *Chronic illness*. 2017: 1742395317715504.
29. Byron G, Ziedonis DM, McGrath C, Frazier JA and Fulwiler C. Implementation of mindfulness training for mental health staff: Organizational context and stakeholder perspectives. *Mindfulness*. 2015; 6: 861-72.

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3 30. Amaro H. Implementing mindfulness-based relapse prevention in diverse
4 populations: Challenges and future directions. *Substance use & misuse*. 2014; 49:
5 612-6.
6 31. Köpke S, Richter T, Kasper J, Mühlhauser I, Flachenecker P and Heesen C.
7 Implementation of a patient education program on multiple sclerosis relapse
8 management. *Patient education and counseling*. 2012; 86: 91-7.
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Figure 1 – NPT core constructs

Table 1 – NPT coding matrix

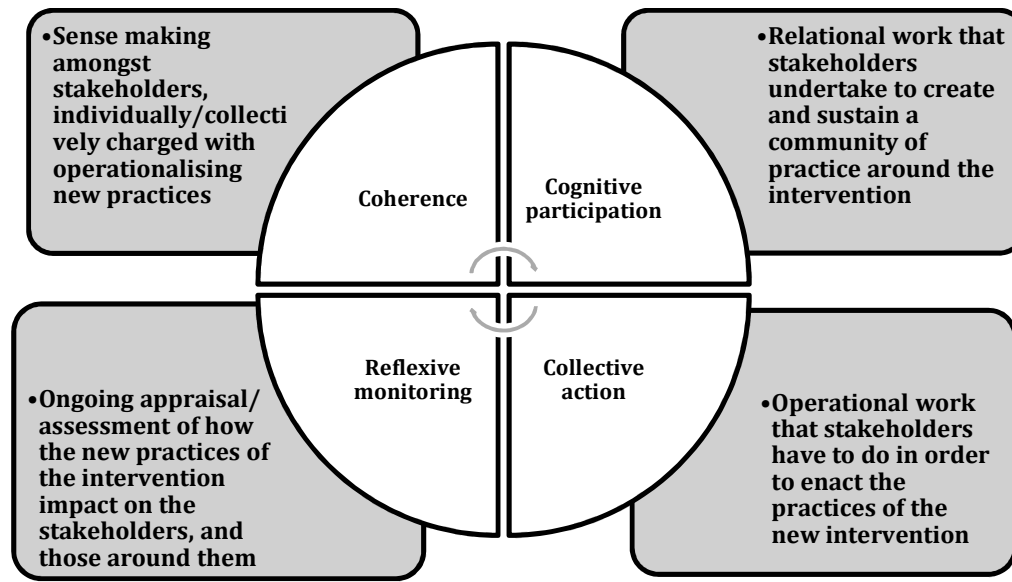


Table 1 – NPT coding matrix

<u>1. Coherence</u>	<u>2. Cognitive participation</u>	<u>3. Collective action</u>	<u>4. Reflexive monitoring</u>
a) Differentiation Is there a clear understanding of how the MBSR course differs from existing practice?	a) Initiation Are key individuals willing to drive the implementation?	a) Interactional workability Does the MBSR course make people's work easier?	a) Systematisation How are benefits or problems identified or measured?
b) Communal specification Do individuals have a shared understanding of the aims, objectives and expected benefits of the MBSR course?	b) Enrollment Do individuals "buy into" the idea of the MBSR course?	b) Relational integration Do individuals have confidence in the MBSR course?	b) Communal appraisal How do groups (patients/ clinicians/ managers/ facilitators) judge the value of the MBSR course?
c) Individual specification Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of the MBSR service?	c) Legitimation Do individuals believe it is right for them to be involved?	c) Skill-set workability How does the MBSR course affect roles and responsibilities/ training needs?	c) Individual appraisal How do individuals appraise the effects on them and their work environment?
d) Internalisation Do individuals understand the value, benefits and importance of the MBSR course?	d) Activation Can individuals sustain involvement with the MBSR course?	d) Contextual integration Is there organisational support for the MBSR course? Are there context issues that matter?	d) Reconfiguration Do individuals try to alter the MBSR course? How do individuals think MBSR needs altered to meet the needs of those with MS?

Additional file 1 – First MBSR group participant semi-structured interview

- 1) How did you find the MBSR course? What were your expectations?
- 2) What worked well in the MBSR course? What didn't? What are your reasons?
- 3) Was the MBSR course helpful or not? In what way?
- 4) Was being in a group an advantage or disadvantage for you? Can you please explain your answer?
- 5) How did you find the setting for the class? What are your reasons for this?
- 6) Were there any barriers to your participation (both in relation to attendance or completion of tasks)?
- 7) What encouraged you to attend and complete homework tasks?
- 8) What are your thoughts on the duration of the course? The time the course took place at?
- 9) What were your experiences of having the homework exercises? Were you able to complete the self-study assignments or not? What factors influenced how much time you spent on the homework assignments?
- 10) Have you noticed any differences since completing the MBSR course? If so, what?
- 11) What aspects of the MBSR course were most/least helpful and why? Can you suggest improvements for future courses?
- 12) Would you recommend MBSR to other people with MS? Why?
- 13) Since completing the MBSR course, have you noticed any effects (positive or negative) on your sense of physical wellbeing? If so, what?

14) Since completing the MBSR course, have you noticed any effects
(positive or negative) on your sense of mental wellbeing? If so, what?

**Additional file 2 – Second MBSR group participant semi-structured
interview**

- 1) How did you find the MBSR course? What were your expectations?
- 2) What worked well in the MBSR course? What didn't? What are your reasons?
- 3) Was the MBSR course helpful or not? In what way?
- 4) Was being in a group an advantage or disadvantage for you? Can you please explain your answer? What was it like being in a group of people specifically made up of people with MS? What was it like being part of a group with other people who were more/less affected with a disability than you?
- 5) How did you find the setting for the class? What are your reasons for this?
- 6) Were there any barriers to your participation (both in relation to attendance or completion of tasks?)
- 7) What encouraged/discouraged you to attend and complete homework tasks?
- 8) What are your thoughts on the duration of the course? The time the course took place at?
- 9) What were your experiences of having the homework exercises? Were you able to complete the self-study assignments or not? Did you require any help to complete the tasks? What factors influenced how much time you spent on the homework assignments?
- 10) Have you noticed any differences since completing the MBSR course? If so, what?

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3 11) What aspects of the MBSR course were most/least helpful for you? Can
4
5 you say why? Specifically:
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- 7 • How did you find the introductory day? How did you find the
8 introductory exercise? Was Mindfulness explained to you? If so,
9 how?
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- 12 • How did you find the Mindful walking practice component?
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 - 14 ○ What worked/did not and why?
 - 15 ○ How was the Mindful walking practice explained to you?
 - 16 ○ Was the Mindful walking practice challenging for you? In
17 what way?
- 18 • How did you find the Mindful movement component?
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 - 20 ○ What worked/did not and why?
 - 21 ○ How was the Mindful movement practice explained to you?
 - 22 ○ Was the Mindful movement practice challenging for you? In
23 what way?
 - 24 ○ How did you find using the home practice CD as compared to
25 in the class? Do you think a visual aid/DVD would be helpful
26 or not? Can you say why?
- 27 • How did you find the Body scan component?
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 - 29 ○ What worked/did not and why?
 - 30 ○ How was the body scan explained to you?
 - 31 ○ What do you think about the duration of the body scan?
 - 32 ○ Did the body scan affect your symptoms? If so, how?
- 33 • How did you find the sitting meditation? What worked/did not and
34 why?
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- How was the sitting practice explained to you?
- What position did you chose to sit in? Were you offered a choice? What position did you sit in if practicing at home? Can you say why?
- Can you suggest improvements for future courses in any of the areas we have covered/or not covered and you feel are important?

12) Would you recommend MBSR to other people with MS? Why?

13) Since completing the MBSR course, have you noticed any effects (positive or negative) on your sense of physical wellbeing? If so, what?

14) Since completing the MBSR course, have you noticed any effects (positive or negative) on your sense of mental wellbeing? If so, what?

Additional file 3 – MBSR instructor semi-structured interview

- 1) How did you find facilitating the MBSR course? What were your expectations?
- 2) What worked well in the MBSR course? What didn't? What are your reasons?
- 3) Do you think the MBSR course was helpful for participants or not? In what ways?
- 4) Was facilitating the course as a group an advantage or disadvantage for you? Can you please explain your answer?
- 5) How did you find the setting for the class? What are your reasons for this?
- 6) Were there any barriers to you in facilitating this course?
- 7) Did you encourage participants to attend and complete homework tasks? If so, how? What kinds of barriers to attendance and completion of homework tasks were mentioned by participants
- 8) What are your thoughts on the duration of the course? The time the course took place at?
- 9) What were your experiences of setting the homework exercises? Did you feel that completion of the standard self-study assignments were realistic or not in this current group? What factors influenced how much time you recommended for the homework assignments?
- 10) Have you noticed any differences in yourself as a mindfulness facilitator since completing the MBSR course? If so, what?

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3 11)What aspects of the MBSR course do you think were most/least helpful
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5 for this group and why? Can you suggest improvements for future
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7 courses?
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9 12)Would you recommend MBSR to other people with MS? Why?
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11 13)What are your thoughts on factors influencing drop-outs' from this
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13 study?
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Additional file 4 – MS Clinician stakeholder semi-structured interviews

- 1) What are your views on Mindfulness-based interventions (MBIs)?
- 2) Can you share your thoughts regarding if/how MBIs differ from other psychological treatments?
- 3) Could you describe your views on the purpose of MBIs?
- 4) Do you think having an MBI available for people with MS would assist in your work? If so, why? If no, why?
- 5) How do you think other MS clinicians view MBIs as a treatment for people with MS?
- 6) What kinds of people with MS do you think would benefit from a MBI?
- 7) Is a MBI something you would consider referring people for? If yes, how would you go about this? If not, what issues would make you unwilling to refer?
- 8) Would you be interested in learning more about MBIs? Would a continuing professional development event be of interest? If yes, why? If no, why?
- 9) What information would you require in order to refer a patient for a MBI?
- 10) What would you want to know about the intervention in order to make a referral?
- 11) What do you think would need to be in place to provide a routine MBI service for people with MS?
- 12) Do you think a MBI for people with MS is something that the local health board could/would support?

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3 13)What sort of feedback would you want/expect from those
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5 running/attending an MBI for people with MS?
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7 14)How would you assess the overall worth of having an MBI service for
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9 people with MS?
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11 15)How would you assess whether an MBI had been worthwhile for your
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13 patient?
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15 16)How would you judge if an MBI service for people with MS was a good
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17 thing or not in the long term? What criteria might stop you referring?
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Table AF5: MBSR; a week-by-week class overview

Class (week) number	Main themes	Home practice (45 minutes daily)
1	Establishment of learning contract Theory underlying mind-body medicine and the development of self-regulatory skills Defining mindfulness Introduction to mindful eating (raisin exercise), mindful breathing, and mindful body awareness	Mindful body awareness via the body scan CD Eat one meal mindfully
2	Focused dialogue, reflection on how individual perception and conditioning affects us Affirming self-responsibility and the role of health-enhancing behaviours	Body scan CD Short sitting practices 10-15 minutes daily Reflecting on the integration of mindfulness into everyday life Pleasant events diary
3	Introducing mindful movement (flexible application of core Hatha yoga postures, mindful locomotion) Group enquiry/discussion of their experiences Review pleasant events calendar	Alternate body scan with mindful movement CD/hand-outs Sitting meditation practice 10-15 minutes daily Unpleasant events diary
4	Body scan, mindful movement, sitting meditation, with emphasis on developing concentration in the practices and an enhanced field of awareness	Alternate body scan with mindful movement CD/hand-outs Sitting meditation practice 20 minutes daily Practicing awareness of stress reactions and behaviours, without taking action to change these Remaining present with 'feeling stuck/ blocking/ numbing/ shutting off'

5	<p>Halfway point.</p> <p>Emphasis on development of adaptation skills, including problem-, emotion-, and solution-focused approaches to coping, and how this relates to being aware, 'staying present', choosing more effective responses, and the development of resilience/ enhanced recovery from stressful experiences</p> <p>Investigating the 'shadow side' of stress responses/ trying to escape difficulty</p>	<p>45 minute sitting practice CD</p> <p>Alternate body scan/ mindful movement</p> <p>Complete difficult communications diary</p> <p>Integrate mindful awareness into daily life experiences</p>
6	<p>Discussion around transformation of stress coping strategies, attitudes and behaviours – developing resilience</p> <p>Emphasis on broadening inner resources and health-promoting attitudes and behaviours, with discussion focused on practical application</p> <p>Particular emphasis on stress and knowing one's feelings during communications, with overview of different communication styles</p>	<p>Alternate sitting meditation with body scan/ mindful movement CDs</p>
7	<p>Mountain meditation, introducing metaphors to reconceptualise the self as 'stable', 'flexible', and 'strong'</p> <p>Review of core MBSR concepts and introducing idea of choice in personal practices, but importance of maintaining 45 minutes daily</p> <p>Loving kindness/ compassion meditation, with strong emphasis on silence, and developing an attitude of loving kindness towards self/others</p>	<p>Choice between all practice introduced thus far</p> <p>Continued 'informal' practice in daily experiences</p>
8	<p>Review of core MBSR concepts.</p> <p>Opportunity to ask any remaining questions.</p> <p>Mostly silent sitting meditation</p> <p>Guided reflection on experience of the course</p> <p>Standard course evaluation forms</p>	<p>Optional, but strongly encouraged to continue with a daily practice of any of the core techniques learned.</p> <p>Integration of practices into daily life.</p>

Additional file 6 – Table AF6: Stakeholder quotes

Number	Data source	Quote
1	P6	<i>'I don't think you can have mixed abilities walking round and everybody happy.. ..I just felt the delivery needed to be a bit more sensitive to the needs of people with MS and MS is very different from chronic fatigue or any other thing like that.. it might have been better to have somebody who has actually been ill or not been well to have an input into the delivery on the course'</i>
2	C4	<i>'I think there are some misunderstandings about what people are expecting to achieve. So I would hope any courses would start off by being clear about what the goals or lack of goals actually are and modify expectations'</i>
3	P9	<i>"..if something happens to me like I couldn't move my arms or my legs I didn't focus on oh I can't do that I just thought I'm going to make them move I'm going to do that and I felt as if other people were oh I've got a pain, oh I've got this, I've got that and I thought I can't do that, I can't sit and listen to that.. .. I wasn't getting anything out of it as in I tend to try and focus on the positivity, the positivity, the exercising, the pushing myself, so I felt as if we were all sitting relaxing, talking, doing meditation and all that, I don't do any of that.'</i>
4	C6	<i>'I would want to know the experience of the facilitator of the group... I would prefer a facilitator who has a bit of experience of MS'</i>
5	C5	<i>'I guess if there was any way of maybe linking in with organisations such as the MS Society there's maybe a bigger scope for getting it out there a bit more if it was kind of a joint venture and there was an element of cross funding, they might be a bit more amenable'</i>
6	P16	<i>'On a personal matter because of the tremor in my right hand I can't write now so if there's anything involving writing I found it personally embarrassing to me because it was barely legible so I didn't like they parts of the course.'</i>
7	I2	<i>'You really had to take on board disability.. .. to see how it played out in people's lives.. ..because we were with them so long and just having to really witness and hear about it'</i>
8	P10	<i>'When I was diagnosed, I mean it hit me quite severely and it was overwhelming and from a personal experience there was so much going on in my life and at the time I was alone with two children and I just was frantic, the whole time thinking "How am I going to manage if this happens again, how am I going to deal with things?" and it helps you put things in perspective. It's not saying "Well that's not going to happen" but it's kind of making you think "Don't stress too much about that, just dwell on the here and the now and what you can do, and don't beat yourself up for things'</i>

		<i>that you can't do", you know. It's taken a lot of pressure off me, I know that whatever could happen might happen, but I'm not as panicked about it as I was before'</i>
9	C4	<i>'It's something I would sort of like to have quick access to for patients, particularly at times of diagnosis which is a time of emotional crisis'</i>
10	C2	<i>'In the new hospital for example here, one of the biggest hospitals in Europe, we do not have any mental health unit!'</i>
11	P18	<i>'A drop in thing would be brilliant. I think we all asked, said we'd love to come back in three months and teach us all again. It's the only course I've ever been on where I would actually be very happy to start at week 1 again because I know how worthwhile it all is and what good it has done me. And with just a bit of discipline from myself will continue for me in the future so I did think it was great.'</i>
12	I1	<i>'Cautious about the walking, very carefully framing that, adapting the mindful movement, making lots of choice, as the body scan, whether people are lying or sitting'</i>
13	C1	<i>'It's whether they come back and say: "that was great" and stuff. "I've had some mindfulness and I feel much better for it." And then if that can be backed up by the clinician, the clinician sending something which suggests, you know, here's the score before and after treatment, that'd be good.'</i>

P – Participant; I – MBSR instructor; C – MS clinician